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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/529,354 09/18/95 FLEISCHMAN S 1928-D-CON

EXAMINER

021836 OM32/0510  
HENRICKS SLAVIN AND HOLMES LLP  
SUITE 200  
840 APOLLO STREET  
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ART UNIT: PAPER NUMBER

3739

DATE MAILED: 05/10/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on January 30, 2001 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

- ☒ Claims 13, 16, 17, 19, 20, 28, 30, 32, 33, 35, 36 + 38-46 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
- ☒ Claims 1-12, 14, 15, 18, 21-27, 29, 31, 34, + 37 have been cancelled.
- ☐ Claims \_\_\_\_\_ are allowed.
- ☒ Claims 13, 16, 17, 19, 20, 28, 30, 32, 33, 35, 36, + 38-46 are rejected.
- ☐ Claims \_\_\_\_\_ are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
- ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
- ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 16, 17, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Altering the length from a first non-zero length to a second non-zero length. (See Ex Parte Graselli, 231 USPQ 393 (Bd. App. 1983), aff'd Mem, 738, F. 2d 453 (Fed. Cir. 1984) and MPEP 2173-05(i)) or, an interface and a separate control device as claimed..

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13, 16, 19, and 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Eggers et al ('443).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al ('443) in combination with Avitall ('297). Eggers et al ('443) teach a device as claimed except for the helical electrode or strip electrode. Avital ('297) teaches the use of a band electrode. It would have been obvious to the artisan of ordinary skill to employ a band electrode as taught by

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Avital ('297) since these are not critical, provides no unexpected result and would enable radially symmetric ablation, thus producing a device such as claimed.

Claims 28, 30, 32, 33, 35, 36, 38, 39 and 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al ('443) in combination with Desai ('198).

Eggers et al teach a device as claimed except manually operable switches each controlling individual electrodes. Desai ('198) teaches the equivalence of computer controlled switches and manually operated switches for controlling ablation. It would have been obvious to the artisan of ordinary skill to employ manually operable switches to control the electrodes in the device of Eggers et al ('443), since this is equivalent to employing computer control, as taught by Desai ('198) or to employ the electrode configuration of Eggers et al ('443) in Desai ('198), since this would allow treatment of a larger area, thus producing a device such as claimed.

Claims 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al ('443) in combination with Desai ('198) as applied to claims 28, 30, 32, 33, 35, 36, 38, 39, and 41-46 above, and further in view of Fogarty et al. Fogarty et al teach the use of a helical electrode for applying energy to the heart. It would have been obvious to the artisan of ordinary skill to employ a helical electrode, since this is useful for applying energy to the heart, and is equivalent to band electrode, thus producing, a device such as claimed.

Applicants' brief description of the illustrated embodiments is noted. The examiner has also reviewed the portion of the specification referred to by applicants in relation to the brief

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description (i.e. page 53-59). However, the examiner does not share applicants' interpretation and determination of that which one having ordinary skill in the art would glean therefrom.

Claim 13 requires, in pertinent part: "control means for electrically coupling the region to a source of tissue ablating energy, selectively electrically altering the energy transmitting characteristics of the region to block transmission from portion of the region while allowing transmission from another portion of the region in response to the first input command and electrically varying the length of the region where transmission is allowed between a first non zero length and a second non-zero length in response to the second input comand". Casting the language in view of the above referred to disclosure, it appears that the "first input command" is to be interpreted as the mode select control discussed at lines 7-17 on page 56 of the instant disclosure, which is expressed as the toggle switch Tm, as set forth in the paragraph spanning pages 57 and 58 of the instant disclosure. Further the "second input command" is interpreted as the actuation of switches TE1-TE7. However, to alter the length from a first non-zero length to a second non-zero length would require that the catheter electrode characteristics be dynamically changed, in the beating heart, while the electrode is energized, before it was moved to a subsequent position. This is a state of affairs one having ordinary skill in the art would find most inadvisable, in the examiners view. This is also reflected in the specification as originally filed at page 51, lines 21-33, wherein it is stated that the probe is first shaped and placed and then energized, with the "shape- and ablate" process being repeated as necessary. As such, given that all electrodes are powered down (i.e. The length of the transmitting region is zero) there is no

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transition from one non-zero length to a second non-zero length contemplated by the originally filed disclosure. Thus the claim language of claim 13 "control means for electrically coupling the region to a source of tissue ablating energy, selectively electrically altering the energy transmission characteristics ... and electrically varying the length of the region where transmission is allowed between a first non - zero length and a second non-zero length in response to the second input command." cannot be supported by the originally filed disclosure, since the region where transmission is allowed is set to zero length before being changed from one length non-zero length to another non-zero length. As it is not whether varying length in general was disclosed, but whether the specific variation directly from one non-zero length to another was contemplated. The examiner maintains that such varying was not disclosed as claimed in the originally filed application, the original text of claim 13, making no mention whatsoever of non-zero lengths, notwithstanding.

Regarding the Eggers et al ('443) reference applicant makes several arguments, which the examiner submits are predicated on an erroneous reading of Eggers et al ('443). In view of the disclosure at column 11, lines 43-46 "by proper selection of metals used for (1) multiplicity electrodes and leads (e.g. Constantan) and (2) guidewire (e.g. steel), each individual electrode can function as a thermocouple..." applicants' argument that "temperature sensors 48 are not specifically associated with any particular electrodes" must fail. Similarly, while the temperature of the plaque is maintained automatically, this does not alter the fact that the electrodes are dynamically switched on or off dependant on the local temperature, thereby

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resulting in a region wherein transmission is allowed being of varying , non-zero lengths with the temperature being the second input command. As applicant has pointed to no explicit or implicit claim limitation which prevents the interpretation of the setting of the temperature in Eggers et al ('443) as the input command, arguments that the power is controlled automatically as a result of the temperature setting (which command is input manually to establish maximum to predetermined temperature), are immaterial.

Regarding applicants contention that there is no support in Eggers et al ('443) for the statement in the previous Office action that the input command from the temperature control knob will cause the interruption of power to some electrodes and not others, the examiner must respectfully disagree. A careful reading of the Eggers et al ('443) disclosure reveals that Eggers et al ('443) specifically teach that "a controlled power supply may be provided which interrupts the power to an individual electrode in the array when the resistance between that electrode and the common electrode falls below a certain level". (emphasis added, column 7, lines 1-5). Thus applicants assertion is not well founded.

Applicant's arguments filed January 30, 2001 have been fully considered but they are not persuasive. .

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.

David Shay:bhw  
April 18, 2001



DAVID M. SHAY  
PRIMARY EXAMINER  
GROUP 330